PCT WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau

INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 2/06 — A2

(11) International Publication Number: WO 95/35072

(43) International Publication Date: 28 December 1995 (28.12.95)

(21) International Application Number: PCT/US94/12467

(22) International Filing Date: 1 November 1994 (01.11.94)

(30) Priority Data:
08/261,420 17 June 1994 (17.06.94) US

(71) Applicant: W.L. GORE & ASSOCIATES, INC. [US/US]; 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US).

(72) Inventor: WALBURN, Frederick, J.; 2000 Rio De Flag, Flagstaff, AZ 86004 (US).

(74) Agents: SAMUELS, Gary, A. et al.; W. L. Gore & Associates, Inc., 551 Paper Mill Road, P.O. Box 9206, Newark, DE 19714 (US).

(81) Designated States: AT, AU, BB, BG, BR, BY, CA, CH, CN, CZ, DE, DK, ES, FI, GB, HU, JP, KP, KR, KZ, LK, LU, LV, MG, MN, MW, NL, NO, NZ, PL, PT, RO, RU, SD, SE, SK, UA, UZ, VN, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE).

Published
With declaration under Article 17(2)(a).
Without abstract; title not checked by the International Searching Authority.

(54) Title: PROTECTIVE SURGICAL SHEATH FOR CORONARY ARTERY BYPASS GRAFTS

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	GB	United Kingdom	MR	Mauritania
AU	Australia	GE	Georgia	MW	Malawi
BB	Barbados	GN	Guinea	NE	Niger
BE	Belgium	GR	Greece	NL	Netherlands
BF	Burkina Faso	HU	Hungary	NO	Norway
BG	Bulgaria	IE	Ireland	NZ	New Zealand
BJ	Benin	IT	Italy	PL	Poland
BR	Brazil	JP	Japan	PT	Portugal
BY	Belarus	KE	Kenya	RO	Romania
CA	Canada	KG	Kyrgystan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo			SE	Sweden
CH	Switzerland	KR	Republic of Korea	SI	Slovenia
CI	Côte d'Ivoire	KZ	Kazakhstan	SK	Slovakia
CM	Cameroon	LI	Liechtenstein	SN	Senegal
CN	China	LK	Sri Lanka	TD	Chad
CS	Czechoslovakia	LU	Luxembourg	TG	Togo
CZ	Czech Republic	LV	Latvia	TJ	Tajikistan
DE	Germany	MC	Monaco	TT	Trinidad and Tobago
DK	Denmark	MD	Republic of Moldova	UA	Ukraine
ES	Spain	MG	Madagascar	US	United States of America
FI	Finland	ML	Mali	UZ	Uzbekistan
FR	France	MN	Mongolia	VN	Viet Nam
GA	Gabon				

Title Of The Invention

PROTECTIVE SURGICAL SHEATH FOR CORONARY ARTERY BYPASS GRAFTS

Field Of Invention

The present invention relates to a tubular sheath for protecting coronary artery bypass grafts such as the internal mammary artery (IMA) and to a method of fabricating an extruded and expanded bio-compatible tubular sheath for this purpose. The invention also relates to a surgical procedure in which a tubular sheath is placed over the graft to be protected when performing bypass graft surgery.

Background Of The Invention

The use of the internal mammary artery as a bypass graft to correct a coronary artery obstruction has been an accepted medical procedure for a number of years. The internal mammary artery, left *in situ* attached to the subclavian artery, is anastomosed to the coronary artery beyond the obstruction. One of the reasons for use of the IMA in coronary artery bypass procedures is the high patency rate compared with saphenous vein bypass grafts.

Because of the substantial utilization of IMA grafts, patients who previously have undergone such procedures are undergoing repeat coronary bypass surgery (termed "re-do" surgery). The IMA is normally dissected with an IMA pedicle and it is particularly susceptible to adhesion formation because of its location and because of the surrounding muscle and tissue associated with its take-down from the mediastinal fat at the chest wall. Generally, most of the pedicle remains outside the closure of the pericardium.

Adhesions to the IMA pedicle make it difficult to identify the IMA and render the IMA susceptible to injury during repeat median sternotomy. Injury to these important vessels that supply critical coronary arteries can be very serious. As a result, medical procedures have been developed which allow quick and easy identification of the IMA pedicle and which protect the IMA pedicle from inadvertent injury when repeat median sternotomies are performed. Damage to a patent IMA can be fatal when the left ventricle is completely dependent on the bypass conduit.

Current procedure involves cutting a segment of synthetic membrane, preferably porous expanded polytetrafluoroethylene of the type sold under the trademark Gore-Tex® Surgical Membrane, to an appropriate length and width. The membrane segment is typically .1 mm thick and is wrapped around the IMA at the end of the operation. Small hemoclips or sutures are then used to hold the edges of the segment together. This creates a protective wrap that extends from the chest wall to the coronary anastomosis on the epicardial surface of the heart. The proximal and distal ends of the wrap are sutured to the proximal pedicle and the epicardium using conventional sutures to prevent the sleeve from migrating.

Repeat or re-do cardiac surgery in the face of a patent IMA artery bypass graft is very tedious and a potentially dangerous procedure. Inadvertent injury to the IMA can induce ischemia, infarction and death. Therefore, slow and meticulous dissection of the area around the IMA in the case of repeat coronary surgery is generally necessary in order to prevent these complications. In the technique described above a segment of Gore-Tex® Surgical Membrane is used to make the identification, isolation and protection of grafts easier.

The use of the Gore-Tex® Surgical Membrane in the manner described above has been described by a number of authors. See for example, "Protection of the IMA Pedicle With Polytetrafluoro-ethylene Membrane", Zehr et al, Journal of Cardiac Surgery, 1993; 8:650-655. Also see, "Internal Mammary Artery Graft At Reoperation; Risks, Benefits and Methods of Preservation", Coltharp et al, Thoractic Surgery, 1991; 52:225-9. "Prevention of Adhesion Formation Around the IMA Artery Pedicle by Gore-Tex Surgical Membrane", Kann et al, European Journal of Cardiothoracic Surgery, Spring, 1993.

Thus, while the procedure of wrapping the IMA in a protective membrane sleeve of polytetrafluoroethylene (hereinafter "PTFE") has met with considerable success and has been shown to prevent formation of adhesives on the chest wall and epicardium, the procedure for making the sheath is an *in situ* operation that requires that the membrane be cut to the appropriate length and width and wrapped around the IMA and clipped together while the proximal and distal ends of the sleeve are respectively sutured to the proximal pedicle and epicardium. Therefore, there exists

a need for an improved and more expedient device and procedure for covering the IMA during CABG surgery.

Summary Of The Invention

The present invention provides a supple protective covering for the IMA and other coronary artery bypass grafts which is supplied as a preformed tubular sheath which the surgeon may easily slip over the IMA or other living blood conduit after dissection and prior to anastomosis of the distal end of the IMA or conduit. Accordingly, in accordance with the present invention, a tubular sheath is provided of bio-compatible material such as expanded, porous PTFE. The sheath is provided in a predetermined wall thickness, typically about 0.4 mm and having a diameter range of approximately 10 to 40 mm. The sheath is provided to the surgeon in sterilized package form and it is necessary only for the surgeon to remove the sheath from the package and slip the sheath over the IMA prior to reattachment of the IMA to the coronary artery beyond the obstruction. The surgeon, at the time of positioning the sheath about the IMA, can trim the sheath to the desired length, if necessary. The sheath may be fastened in place by conventional methods such as suturing, clipping, stapling or with the use of adhesives. Once in place, the sheath assists in isolating the IMA preventing formation of adhesions and scar tissue. The presence of the sheath makes it much easier for the surgeon to identify the IMA in case of re-do surgery, reducing the possibility of injury to the IMA during repeat median sternotomy and also reducing surgery time. The sheath of the invention being flexible and supple, is clampable during re-operation procedures and does not present any seam or suture line along its length.

The sheath of the present invention is fabricated from a bio-compatible material which is preferably porous PTFE. A preferred form is fabricated by extruding and expanding tubular PTFE products to create a tubular article of porous expanded PTFE having a microstructure of nodes interconnected by fibrils. The manufacture of porous, expanded PTFE materials is described by U.S. Patent 4,187,390 incorporated by reference herein. Preferably, in the extrusion apparatus, helical grooves are placed in the extruder tip of the mandrel. The tip is received within a die. The tip is provided with a predetermined back taper which assists in forcing the material into the annular area between the die and tip and into the

grooves in the tip. PTFE resin is mixed with a liquid lubricant and forced under pressure by a ram through the annular area defined by the tip and the die to form extruded tubing. This extrusion method and apparatus is described by U.S. Patent Nos. 4,743,480 and 4,876,051 also incorporated by reference herein.

Thereafter, the extruded tubing is expanded by stretching it at a controlled rate. The stretched tube is longitudinally restrained from shrinking and heat treated in an oven set to above the crystalline melt temperature of PTFE. Once heat treating has been completed, the tube is released from its restraints. It is desirable to have a structure with a fibril length of less than about 5 microns in orderto minimize tissue attachment to the tubular sheath. For expanded PTFE tubes having shorter fibril length on the inner surface than on the outer surface, it may be preferred to evert the tube to place the shorter fibril length on the outer surface. Doing so ensures the least amount of tissue attchment to the outer surface of the tube. Fibril length is measured by cutting a sample tube lengthwise nd then photographing the desired surface, inner and outer, under sufficient magnification. A sufficient number of fibril lengths are measured from the photograph of the sample surface to compute a statistically significant mean fibril length. A fibril length is measured from the edge of one node to the edge of an adjacent node.

The resulting expanded PTFE tube can then be cut into individual sheaths of shorter, predetermined length, as for example 20 cm., and thereafter appropriately packaged and sterilized by conventional sterilization techniques such as autoclaving or gas sterilization.

Brief Description Of The Drawings

The above and other objects of the present invention will be more fully appreciated from the following description, claims and drawings in which:

Figure 1 is a perspective view of a tubular sheath in accordance with the present invention;

Figures 2 to 4 are perspective views showing the steps in coronary artery bypass operation illustrating the positioning of the sheath around the IMA pedicle and re-attachment of the IMA to the coronary artery beyond the obstruction;

Figure 5 is an elevational view of the mandrel portion of the extruder apparatus for extruding sheaths according to the present invention;

Figure 6 is a sectional view of the die;

Figure 7 is a sectional view of the extruder tip taken along line 7-7 of Figure 5;

Figure 8 is a perspective view of an alternate embodiment of a sheath according to the invention;

Figure 9 is a view, partly in section, of the assembled extruder; and

Figure 10 is a schematic diagram setting forth the steps in the method of forming IMA protective sheaths in accordance with the present invention.

Detailed Description Of The Drawings

Turning now to the drawings, the sheath of the present invention is generally as indicated by the numeral 10 and is shown in Figure 1 and is for installation over the IMA as shown in Figures 2 to 4. Tubular implants have been used in the medical industry as replacements for arteries and veins and are generally referred to as prosthetic grafts. The present invention will be described as a tubular sheath as it is not a fluid-carrying conduit but instead serves as a covering about an artery or vein to protect the artery or vein from dissection injury, formation of adhesions and to facilitate identification. While the invention will be described with application to an IMA, it is to be understood that this is a representative description as the sheath may be applied in the same manner in other applications to protect other living blood conduits such as the gastroepiploic artery or saphenous veins.

The sheath 10 comprises a generally tubular body portion 12 that is open at opposite ends 14 and 16. The body is constructed as a tube of material which is inert and bio-compatible and preferably is porous, expanded PTFE. The method of fabricating the sheath as an integral tubular structure will be described hereafter. The sheath is provided to the surgeon in a sterile condition such as in a sterilized package so that it may be removed from the package and positioned over the internal mammary artery. The sheath will have a predetermined length which may vary but typically will be approximately 20 cm. which corresponds to the maximum length of the IMA. The internal diameter of the sheath may vary but would be in the range of 10 to 40 mm so that a loose fit exists between the sheath and the artery. Typically, the sheath is flexible having a wall thickness of about 0.4 mm.

The purpose of the sheath is to provide a covering about the IMA to protect the IMA and to prevent cellular ingrowth and formation of adhesions around the IMA pedicle and also serves to assist to identify the IMA in the case of re-do surgery. Also, since the sheath is flexible, it can be clamped. The sheath may remain in place during re-do surgery if it is not necessary to repair the area encompassed by the sheath.

Figures 2 to 4 illustrate the installation of the sheath of the present invention during coronary artery bypass operation. A median sternotomy is initially performed in conventional manner. The pericardium is opened and the selected right or left IMA is dissected. In this case, the left internal mammary artery 25 is shown in Figure 2 as being dissected from the retrosternum with soft tissue pedicle attached. The sheath 10 according to the present invention has been provided in packaged, sterilized form and is removed from the package and the surgeon cuts the sheath to the desired length. The sheath is then slipped about the distal end of the detached IMA, as seen in Figure 3. The diameter of the sheath is sufficient to allow the sheath to be loosely positioned about the IMA and also facilitates easy positioning of the sheath about the IMA. Re-attachment or anastomosis of the distal end of the IMA at the selected by-pass location is then completed. The sheath, being flexible and supple, may be retracted to allow visual inspection of the IMA. When the procedure is completed, the sheath is extended along substantially the entire length of the IMA. For example, distal anastomosis to the left anterior descending (LAD) coronary artery is a typical by-pass procedure. The sheath may be left in unattached position about the IMA or, if preferred, the surgeon may prefer distal fixation of the sheath to the epicardium using conventional suturing techniques. The surgery is completed by closing the sternum with stainless steel wires. The subcutaneous tissues and skin are closed in layers with appropriate sutures such as polyglactin sutures.

In the event re-do surgery becomes necessary, IMA's which have been wrapped using prior art techniques have exhibited virtually no adhesions between the chest wall and the IMA pedicle with the IMA remaining patent. PTFE membranes have been shown to be relatively impermeable to cellular infiltration, cause minimal adjacent inflammatory response and are resistant to damage by electrocautery. Further, the sheath around the IMA pedicle facilitates visual identification of the

IMA pedicle during re-do operations and provides an adhesion-free plane of dissection for isolation of the vessel. The sheath being flexible is clampable during re-operation procedures.

Various modifications of the sheath construction may also be desirable. For example, as shown in Figure 8, the sheath 10A is constructed having perforations 32 at selected locations formed, for example, by conventional laser cutting techniques. The perforations are provided to relieve potential bleeding complications from the interior of the sheath. Figure 8 also shows a "tail" 36 attached to the sheath. The tail 36 is a string of bio-compatible material attached to the tube 10A and serves to assist the surgeon in locating the sheath and enclosed IMA when performing re-do surgery. The tail may be PTFE and may be bonded or fused to the tube, and suitably colored for better visual identification.

In the event that it is desired, the sheath may be rendered radio-opaque by attaching a radio-opaque material such as a barium strip 38 to the surface of the sheath 10A as shown in Figure 8. Alternatively, the radio-opaque strip may be extruded into the tube when it is fabricated by blending a substance such as barium sulphate into the PTFE resin.

Referring to Figures 2 to 4, the steps in fabricating the sheath of the present invention are shown. The starting material is preferably a paste of PTFE which includes PTFE resin with a liquid lubricant. A tubular billet is preformed and extruded in the extrusion apparatus as shown in Figures 5, 6, 7 and 9. The apparatus will be described more fully hereafter. The extrusion exits the extrusion die in tubular form. Thereafter, the extruded tube is stretched to between 1.5 to 2.5 times its original length. The extruded tube is held in the stretched condition and thermally locked by heating the material. Preferably, the stretch should proceed at a rate of about 200%/sec. The stretched tube is then heated to a temperature above the crystalline melting point of the PTFE, generally at above 327°F.

The material then may be cut to the desired length to form individual sheaths and as indicated; 20 cm. is considered an appropriate length for most graft applications. The sheaths may be suitably packaged and sterilized. Sterilization techniques can be conventional techniques such as gas sterilization or autoclaving.

The apparatus for extruding the sheath 10 includes a hollow cylindrical die 50 housing a tip 56 centrally positioned in the barrel. The die 50 is of substantially uniform internal diameter along its lower end 59 having a conical section 58 at its upper end into which resin is forced. The tip 56 has a slight back taper. The tip 56 and die 52 establish an annulus 60 from which the material is extruded.

A billet of lubricated PTFE is placed in the extruder and a ram, not shown, is activated to force the billet through the annulus 60. Although the tip may be smooth, preferably, the surface of the tip is provided with a plurality of helical grooves 62 pitched at an angle of about between 10° and 85° with respect to the longitudinal axis of the tip.

The following example discloses a preferred example of a process for making the IMA sheath according to the present invention and is set forth for purposes of understanding but not intended to limit the scope of the present invention.

Example 1 - Fabrication Of Expanded PTFE Sheath

An extruder tip was used as described above with reference to Figures 5, 6 and 9, having six helical grooves. PTFE resin (Fluon CD-123 obtained from ICI Americas) was prepared and blended with approximately 120 cc's of Isopar M odorless solvent produced by Exxon Corporation per pound of PTFE to form an extrudate. The extruded material was then compressed into a tubular billet heated and extruded into an 18 mm ID tube in a ram extruder as generally described above in Figures 5 to 9. The extruder tip had a nominal diameter of 18.69 mm and the die had a nominal diameter of 19.46 mm at the discharge end. A back taper of 1 mm per 4.8 cm was provided on the tip. The back taper was provided inwardly from the end of the tip beginning at about 9.53 mm. The tip was provided with a 45° right hand helix groove. The groove had a radius of 1.19 mm and the grooves were equally spaced around the periphery of the tip and the grooves being approximately 0.25 mm deep. The extruded tubing from the die was subsequently processed into individual sheaths as described of porous, expanded PTFE having approximate internal diameter of 17 mm. The stretch conditions were maintained at a temperature of approximately 300°C, a stretch ratio of 2 to 1, with a stretching rate of approximately 200% per second determined by dividing the percentage change in length by the duration of the stretching operation. The stretched tubes were

longitudinally restrained and then placed in an oven set at 350°C for about 40 seconds. Individual sheaths were formed by cutting the tube into 20 cm. segments. The sheaths were then ready for packaging and sterilization procedures to be subsequently performed.

Thus, it will be seen from the foregoing that the present invention provides a sheath for application about grafts such as the IMA which sheath has substantial advantages over the prior art and which provides advantages of protection from dissection, identification and other benefits, particularly important in the event of re-do bypass surgery. With the sheath, the initial surgery is more expedient and re-do surgery much less complicated as visual identification, protection from dissection injury and an adhesion-free plane for dissection of the vessel is provided. As described herein, the sheath is made of a bio-compatible material, preferably a porous, expanded PTFE produced by an extrusion, expansion and heating process. The material is provided to the surgeon in convenient form to minimize the installation time. The sheaths can also be fabricated to provide radio-opacity, if desired. Apertures for relief of potential interior bleeding complications may also be provided.

While the principles of the invention have been made clear in the illustrative embodiments set forth above, it will be obvious to those skilled in the art to make various modifications to the structure, arrangement, proportion, elements, materials and components used in the practice of the invention. To the extent that these various modifications do not depart from the spirit and scope of the appended claims, they are intended to be encompassed therein.

I CLAIM:

CLAIMS:

1. A method of using a tubular sheath of bio-compatible material having opposite ends and having an interior surface and an exterior surface, said method comprising:

(a) surgically exposing a blood conduit of a patient;

(b) dissecting the blood conduit from surrounding tissue;

(c) severing the blood conduit at a distal end thereof;

(d) placing said tubular sheath about the blood conduit by inserting the distal end of the conduit within said interior surface; and

(e) anastomizing the distal end of the blood conduit to a coronary artery with the tubular sheath loosely in place about the blood conduit.

2. The method of Claim 1 wherein said tubular sheath is porous polytetrafluoroethylene.

3. The method of Claim 2 wherein said tubular sheath is comprised of porous expanded polytetraflouroethylene having a microstructure characterized by nodes interconnected by fibrils.

4. The method of Claim 3 wherein said tubular sheath has a fibril length not substantially exceeding 5 microns.

5. The method of Claim 3 wherein said tubular sheath has a shorter fibril length on the exterior than on the interior surface.

6. The method of Claim 1 wherein said tubular sheath includes apertures at predetermined locations in the surface of the tubular sheath.

7. The method of Claim 1 wherein a portion of the tubular sheath includes a radio-opaque material.

8. The method of Claim 1 wherein said blood conduit is an internal mammary artery having a pedicle.

9. The method of Claim 1 wherein said sheath has a microstructure characterized by nodes and fibrils and wherein the fibril length is less than about 5 microns.

10. The method of Claim 1 wherein the blood conduit is an arterial graft.

11. The method of Claim 1 wherein the blood conduit is a venous graft.

12. The method of Claim 1 wherein the blood conduit is the gastroepiploic artery.

13. The method of Claim 1 further including the initial step of providing the tubular sheath in sterile packages.

14. The method of Claim 6 wherein said apertures are laser cut.

15. The method of Claim 7 wherein said radio-opaque material comprises a strip applied to the exterior of the tubular sheath.

16. The method of Claim 7 wherein said radio-opaque material is extruded with the tubular sheath.

. . .

. . .

. . .

. . .

. . .

. . .

. . .

. . .

17. A coronary bypass procedure to protect a blood conduit having a proximal and a distal end, said procedure comprising:

(a) dissecting the blood conduit from surrounding tissue;

(b) transversely severing the blood conduit at the distal end thereof;

(c) providing a flexible, tubular sheath of bio-compatible material having an inner and outer surface and a proximal and distal end;

(d) slipping the sheath loosely over the blood conduit; and

(e) anastomising the distal end of the blood conduit to a coronary artery.

18. The surgical procedure of Claim 17 wherein said sheath is expanded, porous polytetrafluoroethylene.

19. The surgical procedure of Claim 17 wherein said sheath is fastened in place.

20. The surgical procedure of Claim 17 wherein said conduit is an internal mammary artery having a pedicle.

21. The surgical procedure of Claim 19 wherein the proximal and distal ends of the sheath are fastened to the surrounding tissue.

22. The surgical procedure of Claim 17 wherein said sheath has a microstructure characterized by nodes and fibrils and wherein the fibril length is less than about 5 microns.

23. The surgical procedure of Claim 17 wherein the blood conduit is an arterial graft.

24. The surgical procedure of Claim 17 wherein the blood conduit is a venous graft.

25. The surgical procedure of claim 17 wherein the blood conduit is the gastroepiploic artery.

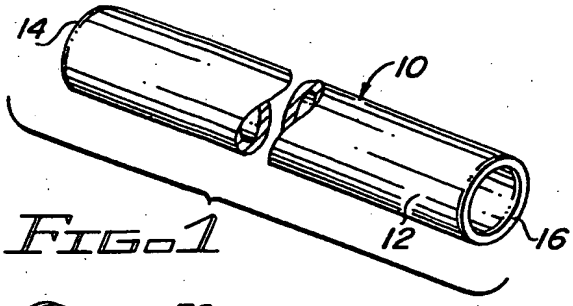

FIG-1

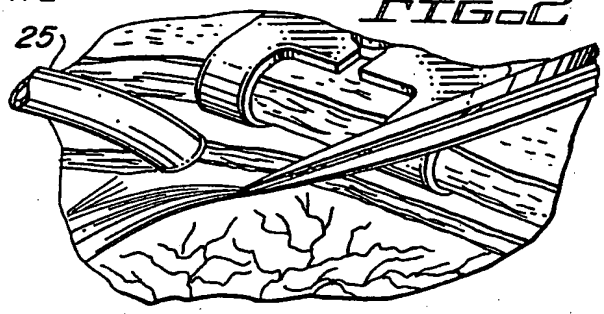

FIG-2

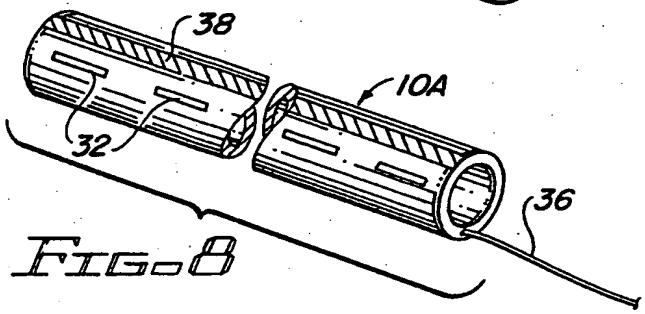

FIG-8

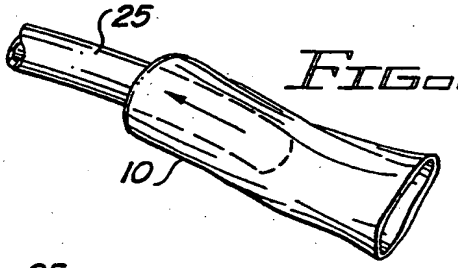

FIG-3

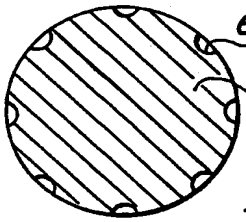

FIG-7

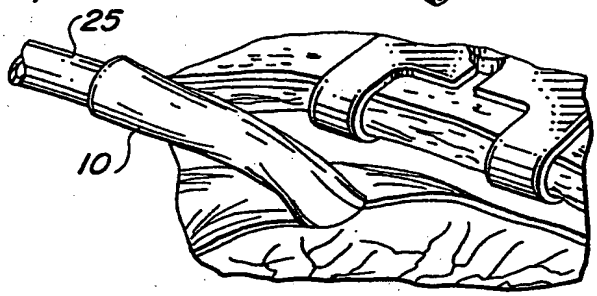

FIG-4

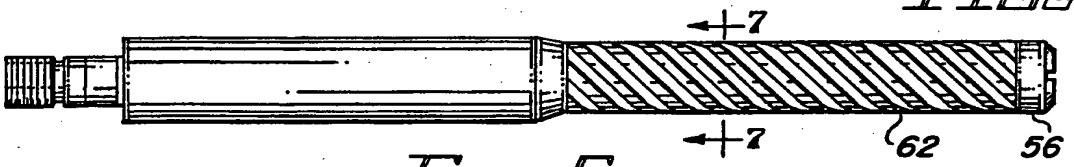

FIG-5

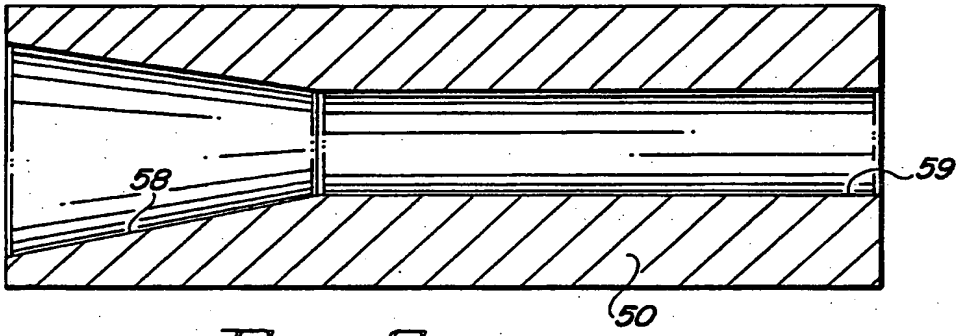

FIG-6

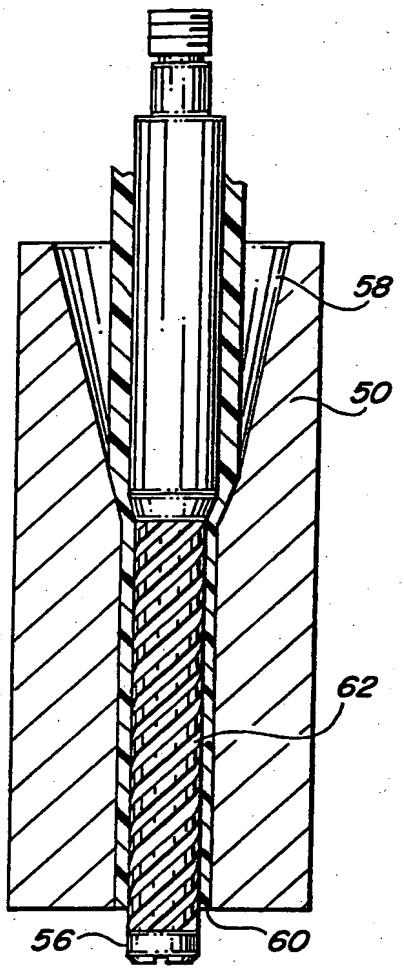
58
50
62
56
60

FIG-9

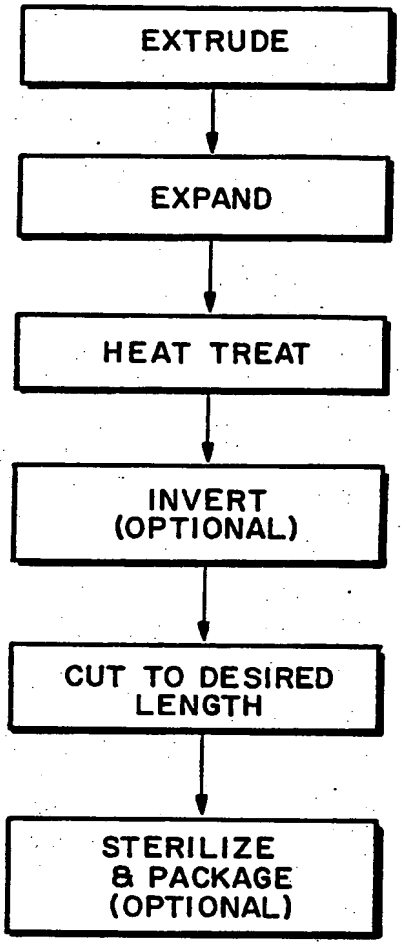
EXTRUDE
EXPAND
HEAT TREAT
INVERT (OPTIONAL)
CUT TO DESIRED LENGTH
STERILIZE & PACKAGE (OPTIONAL)

FIG-10

PATENT COOPERATION TREATY

PCT

DECLARITION OF NON-ESTABLISHMENT OF INTERNATIONAL SEARCH REPORT

(PCT Article 17(2)(a) and Rule 39)

Applicant's or agent's file reference	IMPORTANT DECLARATION	Date of mailing(day/month/year)
MP/73		09/03/95
International application No.	International filing date(day/month/year)	(Earliest) Priority date(day/month/year)
PCT/US 94/ 12467	01/11/94	17/06/94
International Patent Classification (IPC) or both national classification and IPC	A61F2/06	
Applicant		
W. L. GORE & ASSOCIATES, INC.		

This International Searching Authority hereby declares, according to Article 17(2)(a), that **no international search report will be established** on the international application for the reasons indicated below

1. [X] The subject matter of the international application relates to:
   - a. [ ] scientific theories.
   - b. [ ] mathematical theories
   - c. [ ] plant varieties.
   - d. [ ] animal varieties.
   - e. [ ] essentially biological processes for the production of plants and animals, other than microbiological processes and the products of such processes.
   - f. [ ] schemes, rules or methods of doing business.
   - g. [ ] schemes, rules or methods of performing purely mental acts.
   - h. [ ] schemes, rules or methods of playing games.
   - i. [X] methods for treatment of the human body by surgery or therapy.
   - j. [ ] methods for treatment of the animal body by surgery or therapy.
   - k. [ ] diagnostic methods practised on the human or animal body.
   - l. [ ] mere presentations of information.
   - m. [ ] computer programs for which this International Searching Authority is not equipped to search prior art.

2. [ ] The failure of the following parts of the international application to comply with prescribed requirements prevents a meaningful search from being carried out:
   [ ] the description [ ] the claims [ ] the drawings

3. [ ] The failure of the nucleotide and/or amino acid sequence listing to comply with the prescribed requirements prevents a meaningful search from being carried out:
   [ ] it does not comply with the prescribed standard
   [ ] it is not in the prescribed machine readable form

4. Further comments: Meaningful search not possible on the basis of all claims: Method for treatment of the human body by surgery. See Rule 39.1(iv) PCT

Name and mailing address of the International Searching Authority	Authorized officer
European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040, Tx. 31 651 epo nl, Fax: (+31-70) 340-3016	Ms. E. Vonk

Form PCT/ISA/203 (July 1992)